Evaluation proposal to the Danish Health Technology Council regarding PICO◊ Single Use Negative Pressure Wound Therapy System for closed surgical incisions in patients at risk of surgical site complications.

1. Background

1. State the type of health technology

PICO◊ Single Use Negative Pressure Wound Therapy System is class IIb medical device indicated for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include surgically closed incision sites. PICO ◊ single use negative pressure systems are suitable for use both in a hospital and homecare setting. The PICO◊ System is applied by a health care practitioner on closed surgical incisions. Use of the PICO◊ System is with prophylactic intent, post-operatively, with the dressing applied following closure of the surgical incision in the theatre by health care practitioner responsible for closing the incision.

2. Briefly describe the technology and the current Danish clinical context in which the technology will be used.

Summary of technology:

The PICO◊ System is a canister-free single-use negative pressure wound therapy (s-NPWT) system consisting of a single-use sterile pump and a multi-layered adhesive dressing. The PICO◊ System differs from conventional negative pressure wound therapy systems in that it:

- Has no separate canister
- Is portable and disposable
- Has a proprietary dressing layer that is designed to allow even distribution of negative pressure across the incision and zone of injury.

The pump is operated by 2 AA batteries and delivers a continuous negative pressure of 80 mmHg to a sealed wound. Once activated, using a push button, the battery drives the pump for up to 7 days and light-emitting diodes (LEDs) provide alerts for low battery status and pressure leaks.
PICO◊ Dressings come in 10 sizes (Table 1).

PICO◊ Therapy delivers topical negative pressure at 80 mmHg (nominal) to the incision and surrounding zone of injury. Exudate is managed by a combination of absorption into the dressing and evaporation of moisture through the outer film, helping to reduce oedema, hematoma and seroma as lymphatic activity is stimulated. Lateral tension across the incision is also reduced.

The PICO Dressing
The PICO◊ Dressing has also been specifically developed to maximize benefits of the NPWT through its mode of action, which allows:

- Exudate management from 60 to 300 mL per dressing (depending on the size of the dressing);
- Contraction of the incision edges, stimulation of granulation tissue formation, angiogenesis and blood circulation, improvement of drainage and reduction of oedema;
- To reposition the dressing thanks to the siliconized interface.

The PICO◊ Dressing has a very high absorption capacity and enables evaporation. The largest dressing can manage up to 300 mL of fluid (up to 80% evaporates whilst 20% is absorbed), equivalent to a reservoir of a traditional NPWT system. The PICO◊ System has a wide range of dressing shapes and sizes depending on the nature of the closed surgical incision and the amount of exudate to be absorbed. Additional dressings may be purchased separately as required. In addition, PICO◊ Dressings can be combined with gauze and foam fillers when necessary, especially if the wound's depth is greater than 0.5 cm. They are also compatible with compression therapy.

Suction port and tubing:
In order to reduce the risk of injury when pressure is applied to its surface (e.g. if the patient lies or sits on the tubing), the suction port on the dressing is flexible (SoftPort® technology)**.** This feature is particularly useful when compression is used in conjunction with a negative pressure therapy. It also allows the system to function even when bent or twisted, unlike traditional NPWT systems. Consequently, the suction port eliminates pressure points that could delay healing or lead to subsequent lesions on the treated wound, ensuring optimal comfort for the patient, and allowing treatment of complex areas.

Composition of the complete kit:
The PICO◊ System is provided in a sterile, ready-to-use kit for one week of therapy with the PICO◊ Pump and a dressing. In addition, six sterile-packaged fixation strips are included in the sterile compartment containing the dressings. These can be used to reinforce the seal of the dressing if necessary. A slightly to moderately exuding wound can be managed with a kit for up to one week. The dressing is changed when the dressing is saturated or after 7 days of therapy. The PICO◊ System is a single-use device requiring no disinfection procedure and no specific and complex disposal compared to the traditional NPWT devices currently used. NB: Dressing should only be applied and changed by a healthcare professional.

Table 1. PICO Variants.

Product Name	Year of Launch	Content of Kit	Dressing Sizes (cm)
PICO	2011	1 pump + 2 dressings	10 sizes - 10x20, 10x30, 10x40, 15x20, 15x30, 15x15, 20x20, 25x25, small multisite, large multisite
PICO	2011	1 pump + 1 dressing	5 sizes - 10x20, 10x30, 10x40, 15x15, 20x20
PICO 7	2018	1 pump + 2 dressing	10 sizes - 10x20, 10x30, 10x40, 15x20, 15x30, 15x15, 20x20, 25x25, small multisite, large multisite
PICO 7	2018	1 pump + 1 dressing	10 sizes - 10x20, 10x30, 10x40, 15x20, 15x30, 15x15, 20x20, 25x25, small multisite, large multisite
PICO Multipack	2018	Box of 5 dressings	10 sizes - 10x20, 10x30, 10x40, 15x20, 15x30, 15x15, 20x20, 25x25, small multisite, large multisite
PICO 7 Y	2018	1 pump with Y connector + 2 dressings	1 size - Large multisite

What is the principal mechanism of action of the technology?

PICO◊ sNPWT has a multimodal mechanism of action that minimises the risk of non-healing or wound complications, such as surgical site infections (SSIs) and dehiscence in closed surgical incisions.

Evidence suggests that optimal healing of a closed surgical incision can be promoted by managing both the incision site and the surrounding zone of injury. Although traditional NPWT systems have been shown to contribute to improving healing of closed surgical incisions, they were designed primarily to manage chronic wounds through the application of negative pressure to the wound bed. In contrast, the PICO◊ System delivers negative pressure through AIRLOCK◊ Technology which ensures consistent delivery of negative pressure, protecting the incision and treating the wider zone of injury. When applied to closed surgical incisions, PICO◊ sNPWT can contribute to the healing process through multiple mechanisms:

- Protecting the incision from external contamination;
- Providing physical closure of the wound by holding the closed incision together, reducing lateral tensile forces across the incision which can cause the wound to re-open (dehiscence);
- Increasing the activity of the lymphatic system in deep tissue;
- Maintaining an efficient blood supply to the wound (perfusion), which helps support the immune response;
- Increasing the efficiency of functional lymph vessels helping to reduce oedema.

Current Danish Clinical Context

The cost of wound treatment has been predicated to increase significantly in Denmark, fuelled by demographic changes, increasing life expectancy, prevalence of obesity and incidence of background diseases (type 2 diabetes mellitus) (1, 2). Without intervention this could have a major economic burden impact to Demark. This makes the case for new interventions that demonstrate safe, clinical, and cost-effective interventions very compelling.

Surgical site complications defined

In many cases, surgical wounds heal in a predictable way following closure. However, in a significant minority of cases, complications can occur which result in the wound re-opening and requiring further intervention to achieve closure (3).

Surgical site complications include:

- Surgical Site Infections (SSI);
- Wound dehiscence;
- Haematomas/seromas;
- Necrosis, skin/fascial dehiscence or blistering.

Incidence/prevalence of surgical site infections (SSI)

SSI can be classified as:

- Superficial incisional;
- Deep incisional;
- Organ/space infections.

Nice Guidelines NG125 SSI prevention and treatment state that at least 5% (4) of patients undergoing a surgical procedure develop a surgical site infection. A prospective surveillance study of patients undergoing major surgical procedures at a single hospital in England between April 2010 and March 2012, including rigorous post-discharge surveillance, illustrates the scale of under-reporting inherent in routine monitoring (5). The findings report an overall rate of SSI of 5.1%. However, these surveillance studies and audits have

limited data for large bowel surgery (voluntary) and nothing on caesarean section (not offered) which have high contribution to total SSIs per annum (6).

Incidence/prevalence of wound dehiscence

Wound dehiscence, which involves separation of the wound edges along the incision, is considered as a surrogate safety/quality indicator in the United States due to its considerable impact on morbidity, hospital length of stay (LOS) and readmission rates (7, 8). In a retrospective analysis of electronic health data from 25,636 eligible patients who had undergone abdominopelvic surgery in a large hospital system in the USA, 786 (3%) had wound dehiscence (7)**.** The highest prevalence of dehiscence was observed in patients undergoing vascular or hernia surgery where more than 1 in 20 (5.7%) and 1 in 25 (4%) of patients respectively experienced dehiscence. Surgical wound dehiscence negatively impacts patients health-related quality of life and mental health (9).

Risk factors for SSC

The risk of developing a post-operative surgical site complication (SSC) depends on the type of surgery and patient risk factors. Most of the evidence on risk factors for SSI is derived from regression analysis of large observational data sets. These studies were considered by the National Institute for Health & Care Excellence (NICE) as part of the commissioned report on SSI prevention and treatment, which identified several commonly reported risk factors associated with increased likelihood of infection:

- Age;
- Presence of co-morbidities, including diabetes mellitus, renal failure;
- Malnutrition;
- American Society of Anaesthesiologists' (ASA) score of 3 or more;
- Immuno-suppressant treatment (radiotherapy, steroid use);
- Obesity;
- Smoking;
- Wound classification (clean or contaminated);
- Duration of surgery >75% percentile for the procedure.

The presence of just one major risk factor, or two or more moderate risk factors, places patients at an elevated risk of developing an SSC post-operatively and PICO$^{\lozenge}$ sNPWT should be considered for use as described in the World Union of Wound Healing Societies (WUWHS) consensus statement (10).

Table 2. General risk factors for surgical site complication, table adapted from (10) .

Category	Patient-related risk factors	Procedure-related risk factors
Major risk factors Presence of 1 = high risk of surgical site complication	• BMI ≥40kg/m^2 or ≤18kg/m^2 • Uncontrolled insulin dependent diabetes mellitus • Renal dialysis	• Extended duration of surgery • Emergency surgery • Hypothermia
Moderate risk factors Presence of ≥2 = high risk of surgical site complication	• ASA Physical Status >II • Age <1 year or >75 years • BMI 30-39.9kg/m^2 • Diabetes mellitus • Chronic obstructive pulmonary disease ≥GOLD class 2 • Renal insufficiency/chronic kidney disease • Immunosuppression • Steroids for a chronic condition • Chemotherapy • Pre-existing infection at a body site remote from operative site • Serum albumin <2.5g/dL • Smoking (current)	• Anaemia/blood transfusion • High wound tension after closure • Dual antiplatelet treatment • Suboptimal timing or omission of prophylactic antibiotics • Tissue trauma/large area of dissection/large area of undermining
Minor risk factors Presence of any = increased risk of surgical site complications	• African or African American race • BMI 25-29kg/m^2 • Extended pre-operative hospitalisation or residency in a nursing home • Peripheral vascular disease • Congestive cardiac failure with left ventricular ejection fraction <30%	• Failure to obliterate dead space • Location of incision • Previous surgery • Surgical drains

3. Describe the expected patient population

Patients should be treated in line with the existing guidance on SSCs. However, patients with one major risk factor or multiple moderate risk factors should be considered as candidates for PICO$^{◊}$ Therapy (10). This risk assessment should be undertaken prior to surgery and PICO$^{◊}$ Therapy available at the time of surgery. PICO$^{◊}$ Therapy should be used as an alternative care pathway (compared with care with standard surgical dressings) for all patients at-risk of SSCs following closed surgical incisions to help reduce the impact and burden of postoperative SSCs. PICO$^{◊}$ Therapy should be in place for up to 7 days and post-acute care providers should be informed of the use of the dressing.

- Risk assessment prior to surgery to identify PICO eligible patients.
- Replacement of a standard post-operative dressing with PICO$^{◊}$ Therapy at the time of the surgery.
- Advice to the patient and post-acute care provider at the time of discharge on how to manage the PICO$^{◊}$ Device.

Table 3. Scope of the PICO proposal.

Population	Patients having closed surgical incisions with low to moderate levels of exudate who are considered to be at risk of developing post-operative SSCs, particularly SSIs and dehiscence.
Intervention	PICO◊ Single Use Negative Pressure Wound Therapy System
Comparator(s)	Conventional post-surgical wound dressings
Outcomes	The outcomes measures to be considered: • Surgical site infection • Dehiscence • Seroma • Skin necrosis • Length of hospital stay • Adverse events

4. Describe the current status for use in Denmark and abroad

PDF copies of instructions for use, CE mark certificate or equivalent UK regulatory approval such as EC declaration of conformity and quality systems (ISO 13485) certificate attached to submission in Section 6.2**.**

The current version of PICO◊ 7 received CE in 2018 and has been marketed in the Danish healthcare system

FDA Indication expansion 2022

- Regulatory submission to FDA to enable expansion of key indications on the PICO instructions for use (IFU) in the US market
- Evidence package of RCT and prospective observational studies, including 25 studies and 5,673 patients.
- "*When used on closed surgical incisions, PICO 7 Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:* ***Superficial and deep incisional surgical site infections for high risk*** *patients in Class I and II wounds,* ***post-operative seroma and dehiscence****."*

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In Denmark procurement of PICO◊ sNPWT by hospitals is typically done through regional tenders.

5. State completed or ongoing health technology evaluations performed by health technology assessment (HTA) organisations.

Completed Health Technology Evaluations

- **NICE Medical Technology Evaluation Programme** **Medical Technology Guidelines (MTG43) PICO negative pressure wound dressings for closed surgical incisions, 2019**
    - This guideline (MTG43) is currently undergoing a periodic update review.

1.1 Evidence supports the case for adopting PICO negative pressure wound dressings for closed surgical incisions in the NHS. They are associated with fewer surgical site infections and seromas compared with standard wound dressings.

1.2 PICO negative pressure wound dressings should be considered as an option for closed surgical incisions in people who are at high risk of developing surgical site infections.

1.3 Cost modelling suggests that PICO negative pressure wound dressings provide extra clinical benefits at a similar overall cost compared with standard wound dressings.

6. State Danish or international clinical guidelines on use of the technology.

- **WHO guideline on the prevention of surgical site infections** (11)

Conditionally recommends the use of prophylactic NPWT in adult patients on primarily closed surgical incisions in high-risk wounds, for the purpose of the prevention of SSI, while taking resources into account. The guideline provides examples of high-risk wounds such as poor tissue perfusion due to surrounding soft tissue/skin damage, decreased blood flow, bleeding/hematoma, dead space, and intraoperative contamination.

- **NICE Guideline (NG192) Caesarean birth**

Recovery after caesarean birth - Wound care

Consider negative pressure wound therapy after caesarean birth for women with a BMI of 35 kg/m2 or more to reduce the risk of wound infections. [2021] (12)

7. Describe the best existing, widely implemented alternative(s) to the technology.

Conventional post-surgical wound dressings.

2. Clinical outcome and safety

1. Briefly describe the most significant clinical outcomes from the health technology compared with the alternative.

Clinicians apply PICO◊ Therapy to closed surgical incisions to reduce SSCs; therefore, the most significant clinical outcomes that reflect the performance of PICO◊ Therapy are the incidence of surgical site infection (SSI), dehiscence, seroma and skin necrosis. The presence of an SSC can lead to significant patient morbidity, increasing hospital length of stay and costs.

The PICO◊ System has many published studies supporting the safety and performance of the device in closed surgical incisions, in comparison to standard of care (simple foam or gauze dressings, i.e., 'conventional dressings'). The most recently published relevant meta-analysis assessing the clinical performance of PICO◊ Therapy was authored by Saunders *et al* in 2021, who aimed to determine whether the use of PICO◊ Therapy could reduce the incidence of SSCs in comparison to conventional wound dressings in closed surgical incisions in patients at-risk for SSCs. A total of 29 studies were selected from the literature review, of which 11 were RCTs and 13 were observational studies, as well as five conference abstracts. The authors identified a statistically significant reduction in the odds of developing: overall SSI (OR: 0.37; 95% CI: 0.28-0.50; p<0.001), dehiscence (OR: 0.70; 95% CI: 0.53-0.92; p=0.01), seroma (OR: 0.23; 95% CI: 0.11-0.45; p<0.001) and skin necrosis (OR: 0.11; 95% CI: 0.03-0.39; p<0.001) with PICO◊ Therapy, compared to standard dressings. In addition, a significant reduction in the mean length of stay (MD: -1.75; -2.69, -0.81; p<0.001) was also identified with PICO◊ Therapy. The authors concluded that PICO◊ Therapy was effective at preventing certain types of SSCs in patients with risk factors, and that the therapy can aid in the optimization of post-surgical wound treatment pathways.

In support of the current submission, S+N have performed an updated systematic literature review and meta-analysis, capturing comparative studies published up until November 2022. This identified 56 relevant studies, consisting of 28 RCTs, 12 prospective comparative studies, and 16 retrospective comparative studies (see Section 6.3 for full reference list). An overview of the results of the meta-analyses for key SSC outcomes can be seen in Table 4.

Table 4. Results of meta-analyses performed for the most significant clinical outcomes (surgical site complications and length of stay).

Important clinical outcomes	No. of studies	No. of participants	Statistical method	I^2 statistic (%)	Effect estimate	*P*-value
SSI (composite)	33	8359	OR (M-H, common effect, 95% CI)	44	0.59 [0.50- 0.71]	<0.0001*
- Superficial SSI	16	4779		35	0.62 [0.49-0.78]	<0.0001*
- Deep SSI	12	6589		12	0.76 [0.57-1.03]	0.0791
Seroma	19	4345		43	0.55 [0.42-0.73]	<0.0001*
Dehiscence	23	6737	OR (M-H, random effects, 95% CI)	54	0.59 [0.39-0.89]	0.0114*
Skin necrosis	3	746	OR (M-H, common effect, 95% CI)	0	0.15 [0.06-0.39]	0.0001*
Length of Stay	8	757	MD (IV, random effects, 95% CI)	90	-1.96 [-3.23; -0.68]	0.0026*
SSI, surgical site infection; OR, odds ratio; M-H, Mantel-Haenszel; IV, inverse variance. *Denotes statistical significance						

Overall, the findings of this updated systematic literature review and meta-analysis are in alignment with the Saunders *et al* study and therefore demonstrate the consistency and reliability of these findings. The inclusion of 56 articles into the review illustrates the abundance of evidence supporting PICO◊ Therapy and demonstrates the clear benefits of the technology in reducing the odds of SSCs in at-risk patients.

2. Briefly describe the most important risks associated with use of the health technology compared with the alternative.

Adverse event data derived from relevant studies included in Section 2.1 is presented in the Appendix. In summary, the most frequently reported adverse event was skin blistering detected at the closed incision site where a PICO◊ sNPWT was applied. This event occurred more often than with standard dressings, although the same blistering events were also seen with standard dressings. Where reported, these blistering events were often self-limiting and did not require additional intervention to resolve. Blistering is a known risk when using single-use negative pressure wound therapy devices such as PICO◊ sNPWT (13). Other adverse events included incidences of localized bruising, haematoma, itchiness, redness and pain.

Device malfunctions such as the inability to maintain a vacuum, pump noise, battery failure and dressing leakage were also reported. Due to the strict adherence to treatment protocols in clinical trials, these events often resulted in the cessation of therapy with the PICO◊ sNPWT and the subsequent treatment with conventional dressings. Other reasons that led to treatment interruption included patient intolerance or non-compliance with the therapy.

Overall, the adverse events reported in the literature appear to be mild, self-limiting and resolvable upon removal of the device. The identified adverse events that occur with the use of PICO◊ Therapy should be considered within the context of the clinical benefit of the device which has been demonstrated to reduce the incidence of SSI, dehiscence and seroma which can represent a greater burden of morbidity and mortality for patients and caregivers.

3. State ongoing and/or completed clinical studies of the technology in the table.

A complete list of all ongoing and/or completed clinical studies (both comparative and non-comparative in design) relevant to PICO use in closed surgical incisions is presented in Table 5**.**

Table 5. Ongoing and/or completed clinical studies pertaining to PICO in closed incisions.

Study ID	Study design	Participants	Comparator?	Citation
DOI: 10.1097/SLA.0000000000003364	RCT	139	Yes	(14)
DOI: 10.1016/j.arth.2018.12.008	RCT	398	Yes	(15)
DOI:10.1002/jso.25980	RCT	40	Yes	(16)
DOI:10.1302/0301-620x.103b4.Bjj-2020-1603.R1	RCT	462	Yes	(17)
DOI:10.3310/hta24380	RCT	1548	Yes	(18)
DOI:10.1097/sla.0000000000004310	RCT	146	Yes	(19)
DOI:10.1016/j.surg.2020.10.029	RCT	100	Yes	(20)
DOI:10.1089/sur.2019.078	RCT	188	Yes	(21)
DOI:10.1007/s00268-019-05116-6	Meta-analysis	N/A	Yes	(22)
DOI:10.12968/jowc.2018.27.8.520	RCT	110	Yes	(23)
DOI:10.1186/s12891-020-03510-z	RCT	296	Yes	(24)
DOI:10.1097/gox.0000000000002667	Retrospective cohort study	196	Yes	(25)
DOI:10.1093/bjsopen/zraa003	Meta-analysis	N/A	Yes	(26)
DOI:10.1007/s43032-020-00176-9	RCT	155	Yes	(27)
DOI:10.1111/tbj.13659	Prospective cohort study	100	Yes	(28)
DOI:10.1055/s-0040-1705502	RCT	528	Yes	(29)
DOI:10.23750/abm.v91i14-S.10784	Prospective cohort study	65	Yes	(30)
DOI:10.1089/sur.2019.309	Prospective cohort study	200	Yes	(31)
DOI:10.1007/s00266-020-02122-1	Prospective cohort study	26	Yes	(32)
DOI:10.1302/0301-620X.102B8.BJJ-2020-0126.R1	Economic analysis	1540	Yes	(33)
DOI:10.1016/j.jtv.2020.09.005	Economic analysis	119	Yes	(34)
DOI:10.1093/bjsopen/zraa042	Economic analysis	2108	Yes	(35)
DOI:10.1177/1556984520951281d	Prospective cohort study	62	Yes	(36)
DOI:10.1016/j.athoracsur.2020.03.087	Retrospective cohort study	233	Yes	(37)
PMID: 29391117	Retrospective cohort study	61	Yes	(38)
DOI:10.1111/iwj.13376	Retrospective cohort study	154	Yes	(39)
DOI:10.1002/bjs.11642	Retrospective cohort study	71	Yes	(40)
DOI:10.1007/s00266-020-02115-0	Retrospective cohort study	60	Yes	(41)
DOI:10.1111/codi.15332	Retrospective cohort study	435	Yes	(42)
DOI:10.1016/j.ejso.2020.03.176	Prospective cohort study	107	Yes	(43)
DOI:10.1016/j.jhin.2019.11.006	Retrospective cohort study	48	Yes	(44)
DOI:10.1007/s00384-020-03749-x	Retrospective cohort study	32	Yes	(45)
DOI:10.1093/bjs/znab204	RCT	85	Yes	(46)
DOI: gsl.jsp.2018.00004	RCT	50	Yes	(47)
DOI: 10.1136/bmj.n893	RCT	2035	Yes	(48)

Study ID	Study design	Participants	Comparator?	Citation
DOI: 10.1016/j.ajogmf.2021.100410	RCT	110	Yes	(49)
DOI: 10.12968/jowc.2021.30.9.705	Retrospective cohort study	108	Yes	(50)
DOI:10.12968/jowc.2021.30.Sup5.S23	Economic analysis	N/A	Yes	(51)
DOI:10.1016/j.jamcollsurg.2018.12.018	Prospective cohort study	150	Yes	(52)
DOI: 10.1055/s-0041-1731767	Prospective cohort study	952	Yes	(53)
DOI: 10.1177/14574969211043330	Retrospective cohort study	82	Yes	(54)
DOI:10.1111/1471-0528.16710	Retrospective cohort study	59	Yes	(55)
DOI: 10.1097/GOX.0000000000002259	Meta-analysis	2050	Yes	(56)
DOI:10.1186/s12893-021-01446-2	RCT	30	Yes	(57)
DOI:10.1093/bjsopen/zrab116	RCT	100	Yes	(58)
DOI: 10.1136/ijgc-2021-ESGO.657	RCT	26	Yes	(59)
DOI:10.18313/pjrh.2022.xxx	Retrospective cohort study	2788	Yes	(60)
DOI: 10.1097/01.ASW.0000874168.60793.10	RCT	50	Yes	(61)
DOI: 10.1111/1471-0528.15413	RCT	876	Yes	(62)
DOI: 10.1177/1553350615573583	RCT	70	Yes	(63)
DOI: 10.1302/2046-3758.58.BJR-2016-0022.R1	RCT	220	Yes	(64)
DOI: 10.1159/000446550	RCT	59	Yes	(65)
DOI: 10.1097/SLA.0000000000002098	RCT	49	Yes	(66)
DOI: 10.3390/healthcare2040417	RCT	92	Yes	(67)
DOI: 10.1089/sur.2014.145	Retrospective observational study	1948	Yes	(68)
DOI: 10.1111/iwj.12436	RCT	20	Yes	(69)
DOI: 10.1177/1071100715574934	Retrospective cohort study	74	Yes	(70)
DOI: 10.1007/s00264-018-3781-6	Prospective cohort study (with historical control)	94	Yes	(71)
DOI: 10.1155/2015/247324	Retrospective cohort study	36	Yes	(72)
DOI: 10.1016/j.spinee.2014.04.011	Retrospective cohort study	160	Yes	(73)
PMID: 24700216	Prospective cohort study	50	Yes	(74)
DOI: 10.1016/j.ijsu.2014.08.378	Prospective cohort study	50	Yes	(75)
DOI: 10.1177/1553350613496906	Prospective cohort study	30	Yes	(76)
DOI: 10.1089/wound.2017.0749	Prospective cohort study (with historical control)	20	Yes	(77)
DOI: 10.1111/wrr.12615	RCT	68	Yes	(78)
DOI: 10.2478/pjs-2014-0082	RCT	80	Yes	(79)
DOI: 10.1007/s00266-018-1095-0	RCT	64	Yes	(80)
DOI: 10.1097/GOX.0000000000001560	RCT	400	Yes	(81)
DOI: 10.12968/hmed.2015.76.4.217	Prospective cohort study	24	Yes	(82)
DOI: 10.3400/avd.oa.17-00052	Retrospective cohort study	42	Yes	(83)
DOI: 10.1016/j.jhin.2017.10.022	Retrospective cohort study	151	Yes	(84)
DOI: 10.1016/j.ajog.2016.11.670	RCT	120	Yes	(85)

Study ID	Study design	Participants	Comparator?	Citation
DOI: 10.1016/j.ajog.2017.11.067	Retrospective cohort study	759	Yes	(86)
DOI: 10.1111/codi.13798	Retrospective cohort study	71	Yes	(87)
DOI: 10.1093/icvts/ivv204.187	RCT	20	Yes	(88)
DOI: 10.1093/bjs/znab311.109	Retrospective cohort study	NR	Yes	(89)
DOI: 10.1007/s00268-022-06740-5	RCT	377	Yes	(90)
DOI: 10.1097/md.0000000000029641	Retrospective cohort study	360	Yes	(91)
DOI: 10.1093/bjs/znab362.031	Retrospective cohort study	NR	Yes	(92)
DOI: 10.1007/s00402-022-04530-1	RCT	230	Yes	(93)
DOI: 10.1016/j.surg.2022.11.011	RCT	108	Yes	(94)
DOI: 10.3390/jcm10194524	Prospective cohort study	1516	Yes	(95)
DOI: 10.1016/j.jpra.2022.08.003	RCT	20	Yes	(96)
DOI: 10.1097/JU.0000000000001983.08	Retrospective cohort study	206	Yes	(97)
DOI: 10.1038/s41598-022-11856-8	Retrospective cohort study	337	Yes	(98)
DOI: 10.5114/wiitm.2021.106426	Prospective cohort study	30	Yes	(99)
DOI: 10.1016/j.jtv.2016.06.001	Economic Analysis / RCT	87	Yes	(100)
DOI: 10.1016/j.jss.2015.02.008	Economic Analysis	N/A	Yes	(101)
DOI: 10.1111/1471-0528.15573	Economic Analysis	876	Yes	(102)
DOI: 10.1186/s13019-018-0786-6.	Economic Analysis	2621	Yes	(103)
DOI: 10.1111/wrr.12530	Economic Analysis	220	Yes	(104)
DOI: 10.1080/14767058.2019.1611774	Retrospective cohort study	179	Yes	(105)
DOI: 10.1080/08941939.2019.1616009	Prospective cohort study	125	Yes	(106)
DOI: 10.21873/invivo.12192	Prospective cohort study	20	Yes	(107)
DOI: 10.1016/j.ejogrb.2020.08.037	Case series	104	No	(108)
DOI: 10.1590/1413 785220182605196038	Case series	10	No	(109)
DOI: 10.1016/j.jhin.2017.02.023	Case series	399	No	(110)
DOI: 10.1590/1413-785220172502169053	Case series	10	No	(111)
DOI: 10.1111/iwj.12080	Case series	20	No	(112)
DOI: 10.1007/s00266-021-02492-0	Case series	12	No	(113)

Additional studies that were considered relevant to the submission, but which did not possess a digital object identifier (DOI) or PubMed ID, are listed in Table 6.

Table 6. Additional studies relating to PICO in closed incisions.

Study Citation	Study design	Participants	Comparator?
(114) Bullough, L., Burns, S., 2015. Reducing C section wound complications. Clin. Serv. J. 2–6.	Retrospective cohort study	1644	Yes
(115) Bullough, L., Wilkinson, D., Burns, S., Wan, L., 2014. Changing wound care protocols to reduce postoperative and readmission. Wounds UK 10, 84–89.	Retrospective cohort study	660	Yes
(116) Gillespie, B.M., Finigan, T., Kerr, D., Lonie, G., Chaboyer, W., 2013. End users' assessment of prophylactic negative pressure wound therapy products. Wound Pract. Res. 21, 74–81.	Prospective cohort study	15	Yes

Study Citation	Study design	Participants	Comparator?
(117) Wiewiorski, M., 2018. Kanisterlose unterdruck-wundtherapie in der fusschirurgie. Orthopadie & Rheumatolgie 2, 38–40.	Case series	24	No
(118) Foghetti, D., 2016. Single-use negative pression wound therapy: an extra help in preventing and treating surgical incision complications. Acta Vulnologica 14, 152–162.	Case series	10	No
(119) Canonico, S., Campitiello, F., Della Corte, A., Padovano, S., Giannini, S., Luciani, D., Capra, P., Brambilla, R., Mazzei, S., Deotto, L., Chiarenza, S., Corbetta, F., Romanelli, M., Dini, V., Barbanera, S., S, G., 2012. Therapeutic possibilities of portable NPWT. Initial multidisciplinary observation with negative pressure therapy device. Acta Vulnologica 10, 57–64.	Case series	3	No
(120) Timmons, J., Russell, F., 2012. Introducing a new portable negative pressure wound therapy. Wounds UK 8, 47–52.	Case study	1	No

4. State and describe any important data on clinical outcome and safety which has not yet been published.[1]

A literature search was performed in ClinicalTrials.gov to identify ongoing clinical trials involving the PICO◊ Device. Trials that are listed with current statuses as 'completed', 'terminated', 'withdrawn' or 'unknown' were included. A total of 256 articles were identified, of which 26 were deemed eligible for inclusion and are described below in Table 7.

[redacted]

[redacted]

[1] The Danish Health Technology Council may include unpublished and possibly confidential data concerning clinical outcome and safety in its evaluations, provided that a number of criteria have been met. See the principles from the Danish Health Technology Council for use of unpublished data on the Danish Health Technology Council's website.

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
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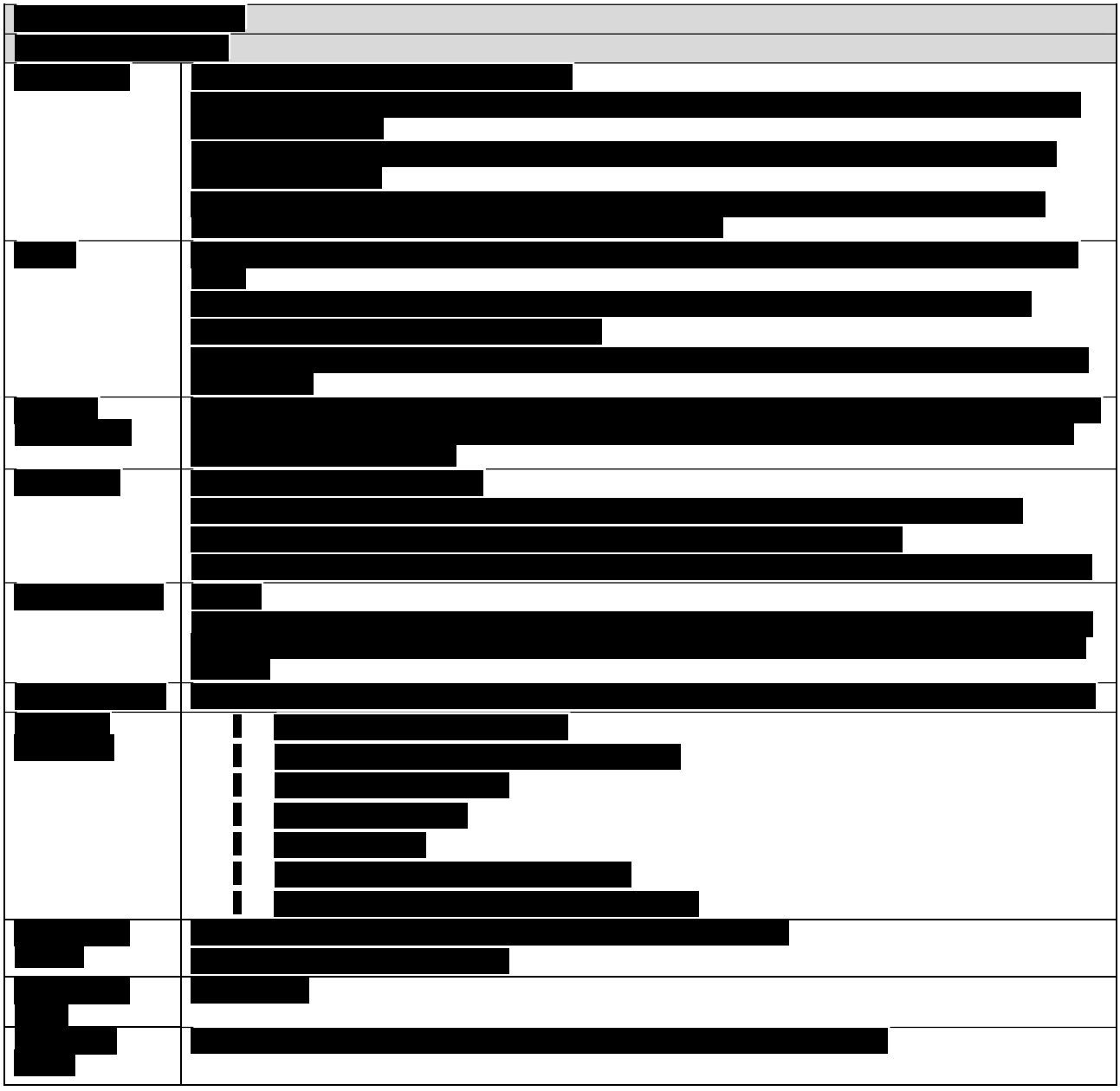
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Further ongoing trials that the manufacturer is aware of are included in the table below. Note that these data are academic-in-confidence.

[redacted]



3. Patient perspective

1. State and describe data concerning patient experience as regards the choice between the technology and comparator(s).

A study which looked at patient experience using PICO™ dressing concluded it can be used with little discomfort to most patients after elective vascular surgery (121)**.**

The objective was to explore patients' experiences wearing the PICO™ dressing for 7 days. Nine men and 6 women were interviewed, and analysis was conducted using qualitative content analysis.

The PICO™ dressing system was well accepted by most patients. Most prominent problems were fear of dropping the pump to the floor, lack of information, and initial feelings of uncertainty. Four patients who had the PICO™ and standard dressing in opposite groins simultaneously, preferred the PICO™ dressing.

2. State and describe any issues regarding accessibility and inequality for specific patient groups in use of the health technology.

A number of population groups have potential special considerations for equality. PICO may be beneficial to women who have had obstetric, gynaecology and breast surgery. Certain ethnic groups are more prone to poor wound healing due to increased risk of diabetes or keloid formation and older population are also more at risk of poor wound healing. One of the risk factors for wound complication is malnutrition which may be more prevalent in lower income parts of community. There appears to be a correlation between obesity and level of education with prevalence generally higher in lower education level across most ages (1).

4. Organisation

1. State and describe the organisational conditions in the health care sectors which are likely to be changed or influenced if the Danish Health Technology Council recommends use* of the health technology.

The product is available on all hospitals in Denmark including communities, both areas through tenders. This means that when a patient is discharged from hospital with the product, the homecare/community easily can carry on the same treatment.

The product is used treating hard to heal wounds and surgical wound complications by the community nurses. In Aalborg community they have completed a project to demonstrate accelerated wound healing with early treatment on trauma and surgical wounds to prevent these types of wounds from becoming difficult-healing wounds.

The product is current available both in hospital and community in Denmark with no issues in relation to IT and hardware. Integration in the system has been and will continue to be smooth with very limited drain on resources.

Smith + Nephew has a dedicated team of Key Account Managers and Product Specialist who deliver training on a continuous basis to healthcare practitioners. This has been ongoing in hospital departments where the product is current been used.

Training is carried out both on local demand, but also as full educational days where the content is clinical as well as hands on workshops. The participants are from both hospitals and community, to secure the best possible patient journey.

We also have network groups throughout the country, where Wound care nurses meet twice a year and discuss experience as well as knowledge share. This is also cross sectoral, to ensure input from both working environments.

We have also in cooperation with healthcare professionals developed patient cases, showing evaluation of the product or how to use the product best possible on different kind of wounds.

2. Describe current experience with the health technology and its use.

We work with the surgical department and team to identify which patients are most at risk of developing a post-surgical complication (infection, seroma, or dehiscence). This will be from prospective data review and clinical experience. From this a pathway is developed to allow for appropriate use of the product and to achieve the greatest outcomes in line with our data.

Instruction to AHA patients, Hvidovre hospital

Hvidovre Hospital Gastroenheden	Instruks til brug af PICO	Ansvarlige: Overlæge Ida Lolle Afd. læge David F. Scheifte Overlæge Morten Laksafoss Lauritsen	Sept. 2021

Instruks for anvendelse af PICO til AHA-patienter

Baggrund

Sårinfektioner er en hyppig kirurgisk komplikation til akutte laparotomier. Infektioner medfører forlænget indlæggelse, flere interventioner og større ubehag for patienten.
Anvendelse af PICO har i en række studier vist at kunne reducere forekomsten af sårinfektioner samt seromdannelse.

Vi har i det akutte kirurgiske team på Gastroenheden, Hvidovre Hospital derfor valgt, at der skal overvejes anvendes PICO til alle akutte laparotomier, særligt ved forekomst af risikofaktorer udover det akutte kirurgiske indgreb.

Formålet med denne instruks er at sikre ensartet forbrug af utensilier i forbindelse med brug af PICO vacuumpumpe samt at sundhedspersonalet håndterer PICO korrekt.

Hvad er PICO?

PICO er en forbinding til kirurgiske sår, hvor der etableres et 80 mmHg undertryk i forbindingen. Herved opsuges sårets ekssudat, der fordamper gennem forbindingen. Karrene stimuleres til hurtigere angiogenese og serom og ødem reduceres.
Pumpen har en levetid på 7 dage.

Hvilke patienter skal have PICO?

Alle patienter der får foretaget en akut laparotomi er i øget risiko for sårkomplikationer. Vores anbefaling er derfor, at hvis der samtidig forekommer andre risikofaktorer for sårkomplikationer (se nedenfor) skal anvendelse af PICO overvejes af operatøren.

Her følger en liste over udvalgte risikofaktorer for sårkomplikationer:

- Kontamineret operationsfelt (diffus peritonit, fækulent spild, tomi på hulorgan etc.)
- Septisk patient
- Aterosklerosestigmatiseret patient (iskæmisk hjertesygdom, TCI/apoplexi, perifer arteriel sygdom)
- Aktiv ryger
- Diabetes mellitus
- Levercirrose
- Immunsuppression
- Stort subcutant fedtlag

Behandlingsansvar

PICO anlægges af OP personale, læger eller sygeplejersker.

- Der skal tilstræbes et jævnt underlag. Dette kan evt. gøres ved at flytte bandagen lidt til den ene side. PICO-bandagen behøver ikke sidde centralt for at virke.
- Ved mindre ujævnheder placeres dobbeltklæbende tape (Renasys Gel) på huden under klæbekanten af PICO-bandagen
- PICO-bandagen tilsluttes pumpen og aktiveres ved at trykke på den orange knap.
- Kantfikseringsstrimlerne sættes rundt i kanten, dog uden at der overlappes på den hvide del af bandagen.
- PICO skiftes hver 7. dag, hvis det vurderes, at der er behov for VAC-terapi i mere end de syv dage pumpen virker.

Billeder af mætningsgrad

Sådan håndteres PICO postoperativt

Når forbindingens kapacitet til at fordampe ekssudat fra såret er overskredet, skal forbindingen fjernes eller skiftes. Forbindingen vil typisk skulle skiftes 1 – 2 gange i ugen. Det er tydeligt at se hvornår bandagen er mættet og skal skiftes. Ydermere er der en alarm på enheden, der fortæller hvis bandagen skal skiftes eller ikke kan holde tæt.

Skulle det være nødvendigt at se til såret, f.eks. ved mistanke om infektion, fascieruptur mv., løft da blidt på bandagen og fikser igen efterfølgende med film. Det kan være nødvendigt at skifte hele bandagen og fiksere pæny.
Vi anbefaler at såret tilses hvis der efter postoperative dag 1 tilkommer "snask" o.l. på forbindingen, og rutinemæssigt på 4./5. postoperative dag.

Hvis patienten udskrives med PICO, skal plejepersonalet instruere patienten i, hvordan patienten selv seponerer PICO i hjemmet. Kan patienten ikke selv håndtere seponering af PICO, skal der bestilles hjemmesygeplejerske til dette. Såret skal være tilset af læge mindst en gang i forløbet inden patienten udskrives.

PICO størrelser i sortiment på kirurgisk afdeling, Gastroenheden, Hvidovre Hospital:

Varenr.	Varebeskrivelse	Str.
66802002	PICO 7 med 2 bandager	10 x 20 cm
66802003	PICO 7 med 2 bandager	10 x 30 cm
66802004	PICO 7 med 2 bandager	10 x 40 cm
66802005	PICO 7 med 2 bandager	15 x 15 cm
66801082	Renasys Adhesive Gel Patch	10 x 7 cm

Plejepersonalet i sengeafdelingen har ansvar for at pleje og observere forbinding samt pumpe mindst en gang i hver vagt.
Ved gennemsivning/blødning kontaktes læge.

Patienten kan mobiliseres frit når de behandles med PICO. Der kan udleveres informationspjece til patienten, som findes her PICO patientvejledning.pdf

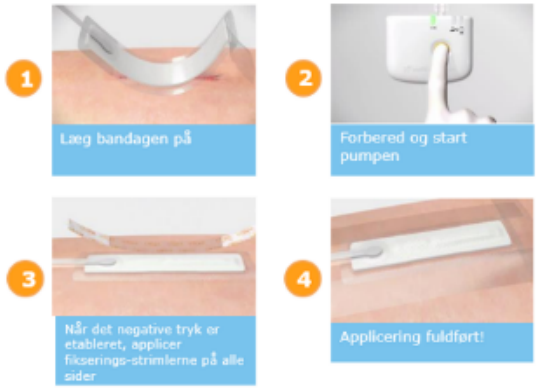
Forberedelse

Vælg en PICO-bandage, der også dækker den omgivende hud, således at effekten af kapillærdannelsen og reducering af ødem også virker her. Jo større PICO-bandage des større væskehåndtering.

Klargøring af sår og såromgivelser

- Al behåring fjernes i det område hvor PICO og kantsikring kommer til at sidde.
- Såret renses og eventuelle nekroser og fibrin fjernes.
- Huden omkring såret renses og tørres.

Sådan anvendes PICO til lukkede incisioner



- PICO-bandagen placeres over såret uden at trække i den. Det sikres at sugehovedet vender op mod patientens ansigt.

Figure 3. Instruction to AHA patients, Hvidovre Hospital.

Figure 4.

5. Budget and finances

1. State and describe a list of published peer-reviewed economic analyses of the technology

A systematic review was conducted to identify cost-effectiveness studies of relevant interventions for the prevention of surgical site complications (SSC) following closed surgical incisions. The review updated the searches that were conducted in 2018 for the NICE technology appraisal focusing mainly on PubMed, and Embase (122). We also used our knowledge of new publications that we informally track internally.

In addition to the 5 studies that were presented in the NICE guideline (100, 123-125), and one unpublished obtained through contacts with authors Galiano et al (126), we found 5 additional studies (127-131).

All 10 full economic evaluations evaluated the cost-effectiveness of PICO compared to standard of care (SC) in the prevention of SSC following closed surgical incisions. The studies are of moderate to good quality. 8 of the 10 studies demonstrated that PICO is cost saving while 2 showed PICO is a cost-effective intervention in preventing SSC. The overall conclusion from these studies is that PICO provides value for money to the healthcare payers and patients as summarised in Table 9.

Table 9. Summary Results of studies comparing PICO and standard of care in closed surgical incisions.

Author	Surgical procedure	Type of Economic evaluation	Summary findings
Murphy 2021	Breast surgery	CUA	Cost saving
Wagner 2023 (in press)	Orthopaedic (NoF)	CCC	Cost saving
Irwin 2020	Breast surgery	CCC	Cost saving
Tormey (2021)	Breast surgery	CCC	Cost saving
Nherera 2021	6 different types	CUA	Cost saving
Nherera 2018	CABG	CUA	Cost saving
Nherera 2017	Orthopaedic	CUA	Cost saving
Hyldig 2020	C-Section	CUA	Cost-effective
Heard 2016	C-Section	CUA	Cost saving
Galiano- unpublished	Breast surgery	CEA	Cost-effective
CUA, cost utility analysis, CEA, Cost-effectiveness analysis, CCC; cost consequence analysis, NoF; neck of femur fracture repair			

2. Describe the overall results from the completed outline of costs*.

The estimated total cost per patient treated with PICO is [redacted]. while that of standard of care is [redacted] resulting in a cost saving of [redacted] per treated patient in the base case cost model See Figure 4.

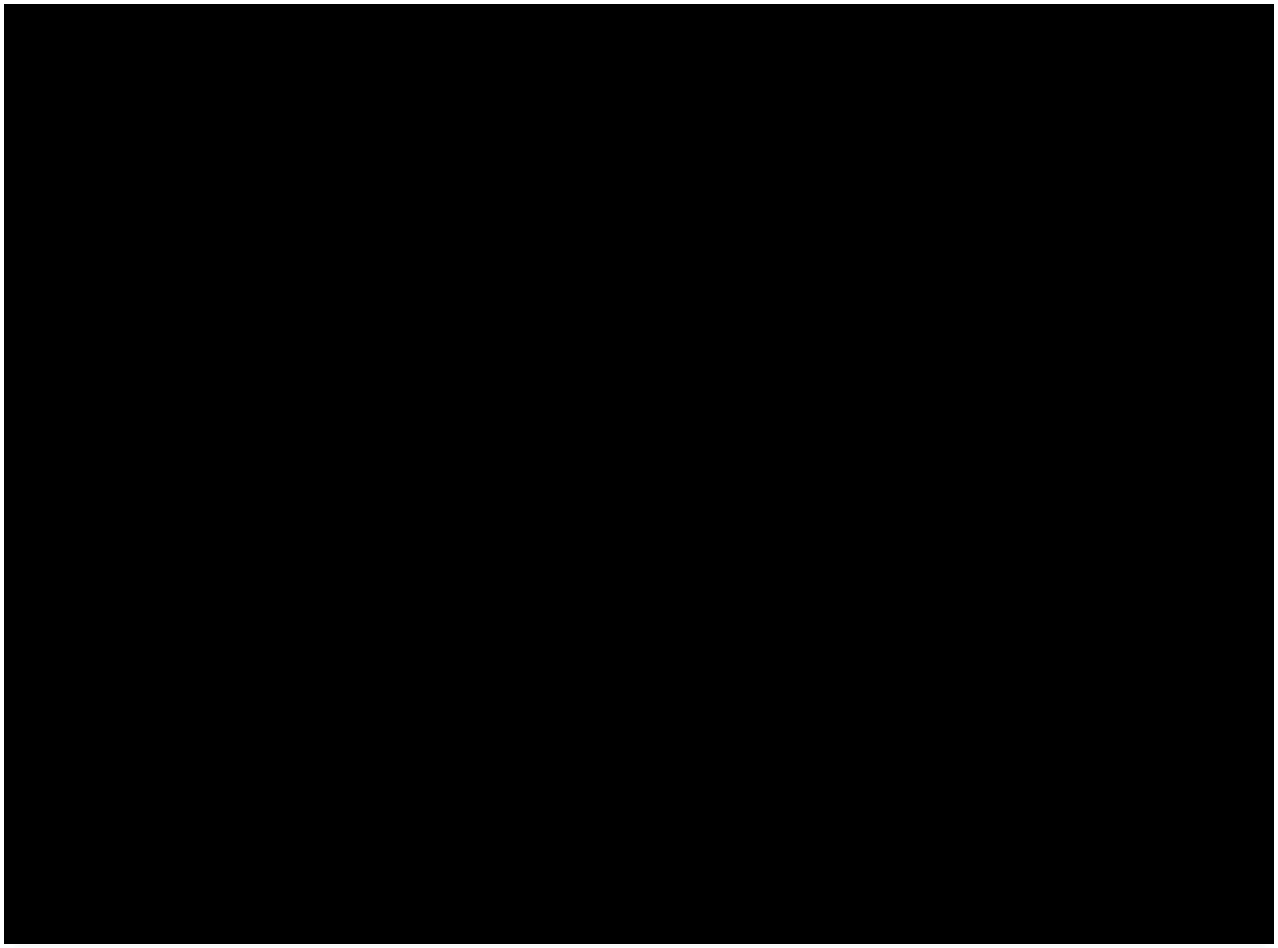


Figure 5. Base case cost model for PICO compared to standard of care in surgical incisions.

Conclusions

The cost model estimated that prophylactic use of PICO following surgical incisions is a cost-saving intervention. We estimated saving of up to [redacted] per patient and these results remained robust in various sensitivity analysis.

6. Other relevant enclosures

Relevant publications and documents will go to the Danish Health Technology Council secretariat, but they will not be forwarded to the Council for their decision. However, applicants may choose to insert references to publications, for example hyperlinks, so the Council can search them itself.

1. State and attach relevant publications on the health technology.

1. WORLD UNION OF WOUND HEALING SOCIETIES CONSENSUS DOCUMENT, Closed surgical incision management: Understanding the role of NPWT

WUWHS Consensus Document.pdf

2. Saunders C, Nherera LM, Horner A, Trueman P. Single-use negative-pressure wound therapy versus conventional dressings for closed surgical incisions: systematic literature review and meta-analysis. BJS Open. 2021;5(1).

Saunders et al 2021.pdf

2. State and attach relevant documents on the health technology.

PICO 7 EU DoC HU 142 v015.pdf

PICO 7Y HU_158 EU DoC Issue 5.pdf

PICO Soft Port EU DoC HU_065 v17.pdf

SN Medical CE00356 EXP 26May24 (1).pdf

SN Medical Ltd (Hull) ISO 13485_Exp18Oct2

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